

Amendment and Response Under 37 C.F.R. 1.116

Applicant: Cynthia T. Clague et al.

Serial No.: 10/694,037

Filed: October 27, 2003

Docket No.: M190.242.101/P-11210.00

Title: METHOD AND APPARATUS FOR MAKING PRECISE INCISIONS IN BODY VESSELS

IN THE CLAIMS

No changes are made to the claims in this response.

1. (Previously Presented) A vessel wall cutting instrument for making an elongated slit through a vessel wall of a body vessel of a patient having a vessel axis from an exterior surface to an interior surface of the vessel wall into a lumen of the body vessel comprising:

an elongated instrument shaft extending between a shaft proximal end and a shaft distal end and having an instrument shaft axis the elongated instrument shaft comprising a fixed shaft member and a movable shaft member adapted to move with respect to the fixed shaft member in the direction of the instrument shaft axis;

a fixed cutting blade fixed to the fixed shaft member at the shaft distal end to extend substantially laterally to the instrument shaft axis to a fixed cutting blade free end, the fixed cutting blade having a blunt distal leading blade side, a proximal, trailing side having a fixed cutting edge, and a cutting tip at the fixed cutting blade free end;

wherein the fixed cutting edge of the proximal trailing side is generally straight along the direction of the laterally extending fixed cutting blade, and wherein the blunt distal leading blade side includes a major portion spaced-apart from the cutting tip, wherein the major portion extends generally perpendicular to the proximal trailing side;

a movable cutting blade having a distal, leading edge fixed to the movable shaft member at the shaft distal end, the movable cutting blade extending substantially laterally to the shaft axis and having a movable cutting edge along the movable cutting blade distal, leading edge;

means for maintaining the movable shaft member in a retracted position with the movable cutting blade spaced proximally from the fixed cutting member as the blunt distal leading blade side is applied against the exterior surface of the vessel wall to depress the vessel wall and is moved laterally to pass the cutting tip of the fixed cutting blade through the vessel wall and into the lumen of the body vessel; and

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means for moving the movable shaft member with respect to the fixed shaft member between the retracted position separating the fixed and movable cutting edges and an extended position wherein the fixed and movable cutting edges are substantially in side-by-side alignment to shear the vessel wall and form a slit therein.

2. (Original) The vessel wall cutting instrument of Claim 1, wherein:

the fixed cutting blade is disposed to extend laterally to the shaft axis by a shank having a shank proximal end mounted to the fixed shaft member at the shaft distal end and extending distally substantially in parallel with the instrument shaft axis and alongside the movable cutting blade to a shank distal end; and

the fixed cutting blade extends laterally to the shaft axis from the shank distal end to the fixed cutting blade free end and has a substantially straight fixed cutting edge,

whereby the cutting tip at the fixed cutting blade free end is disposed against a body vessel wall substantially in alignment with the vessel axis as the blunt distal leading blade side is applied against the exterior surface of the vessel wall to depress the vessel wall and is moved laterally to pass the cutting tip of the fixed cutting blade through the vessel wall and into the lumen of the body vessel.

3. (Original) The vessel wall cutting instrument of Claim 2, wherein:

the means for maintaining the movable shaft member in a retracted position comprises a spring mounted between the fixed shaft member and the movable shaft member and exerting retraction force therebetween; and

the moving means comprises means for transmitting force overcoming the retraction force to the movable shaft member to move the movable shaft member with respect to the fixed shaft member between the retracted position and the extended position.

4. (Original) The vessel wall cutting instrument of Claim 2, further comprising means for applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.

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5. (Original) The vessel wall cutting instrument of Claim 2, further comprising means for applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.
6. (Original) The vessel wall cutting instrument of Claim 2, further comprising means for applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.
7. (Withdrawn) The vessel wall cutting instrument of Claim 2, wherein the moving means further comprises an elongated, flexible, remote control comprising a flexible cable extending from the movable shaft member through a flexible tube to a remote plunger adapted to be manipulated to transmit force through the flexible cable to overcome the retraction force.
8. (Withdrawn) The vessel wall cutting instrument of Claim 7, further comprising means for applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.
9. (Withdrawn) The vessel wall cutting instrument of Claim 7, further comprising means for applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.
10. (Withdrawn) The vessel wall cutting instrument of Claim 7, further comprising means for applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.
11. (Withdrawn) The vessel wall cutting instrument of Claim 1, wherein the moving means further comprises an elongated, flexible, remote control comprising a flexible cable extending

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from the movable shaft member through a flexible tube to a remote plunger adapted to be manipulated to transmit force through the flexible cable to move the movable shaft member with respect to the fixed shaft member between the retracted position and the extended position.

12. (Withdrawn) The vessel wall cutting instrument of Claim 11, further comprising means for applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.

13. (Withdrawn) The vessel wall cutting instrument of Claim 11, further comprising means for applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.

14. (Withdrawn) The vessel wall cutting instrument of Claim 11, further comprising means for applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.

15. (Original) The vessel wall cutting instrument of Claim 1, further comprising means for applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.

16. (Original) The vessel wall cutting instrument of Claim 1, further comprising means for applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.

17. (Original) The vessel wall cutting instrument of Claim 1, further comprising means for applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.

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18. (Previously Presented) A vessel wall cutting instrument for making an elongated slit through a vessel wall of a body vessel of a patient having a vessel axis from an exterior surface to an interior surface of the vessel wall into a lumen of the body vessel comprising:

an elongated instrument shaft extending between a shaft proximal end and a shaft distal end and having an instrument shaft axis the elongated instrument shaft comprising a first shaft member and a second shaft member adapted to move with respect to one another in the direction of the instrument shaft axis;

a first cutting blade fixed to the first shaft member at the shaft distal end to extend substantially laterally to the instrument shaft axis to a first cutting blade free end, the first cutting blade having a blunt distal leading blade side, a proximal, trailing side having a first cutting edge, and a cutting tip at the first cutting blade free end;

wherein the first cutting edge of the proximal trailing side is generally straight along the direction of the laterally extending first cutting blade, and wherein the blunt distal leading blade side includes a major portion spaced-apart from the cutting tip, wherein the major portion extends generally perpendicular to the proximal trailing side;

a second cutting blade having a distal, leading edge fixed to the second shaft member at the shaft distal end, the second cutting blade extending substantially laterally to the shaft axis and having a second cutting edge along the second cutting blade distal, leading edge;

means for maintaining the first and second shaft members in a retracted position with the second cutting blade spaced proximally from the first cutting blade as the blunt distal leading blade side is applied against the exterior surface of the vessel wall to depress the vessel wall and is moved laterally to pass the cutting tip of the first cutting blade through the vessel wall and into the lumen of the body vessel; and

means for moving the first and second shaft members together from the retracted position to bring the first and second cutting edges substantially in side-by-side alignment to shear the vessel wall therebetween and form a slit therein.

19. (Original) The vessel wall cutting instrument of Claim 18, wherein:

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the first cutting blade is disposed to extend laterally to the shaft axis by a shank having a shank proximal end mounted to the first shaft member at the shaft distal end and extending distally substantially in parallel with the instrument shaft axis and alongside the second cutting blade to a shank distal end; and

the first cutting blade extends laterally to the shaft axis from the shank distal end to the first cutting blade free end and has a substantially straight first cutting edge,

whereby the cutting tip at the first cutting blade free end is disposed against a body vessel wall substantially in alignment with the vessel axis as the blunt distal leading blade side is applied against the exterior surface of the vessel wall to depress the vessel wall and is moved laterally to pass the cutting tip of the first cutting blade through the vessel wall and into the lumen of the body vessel.

20. (Original) The vessel wall cutting instrument of Claim 19, wherein:

the means for maintaining the first and second shaft members in a retracted position comprises a spring mounted between the first shaft member and the second shaft member and exerting retraction force therebetween; and

the moving means comprises means for transmitting force overcoming the retraction force to move the second shaft member with respect to the fixed shaft member between the retracted position and the extended position.

21. (Original) The vessel wall cutting instrument of Claim 19, further comprising means for applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.

22. (Original) The vessel wall cutting instrument of Claim 19, further comprising means for applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.

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23. (Original) The vessel wall cutting instrument of Claim 19, further comprising means for applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.

24. (Withdrawn) The vessel wall cutting instrument of Claim 19, wherein the moving means further comprises an elongated, flexible, remote control comprising a flexible cable extending from the second shaft member through a flexible tube to a remote plunger adapted to be manipulated to transmit force through the flexible cable to overcome the retraction force.

25. (Withdrawn) The vessel wall cutting instrument of Claim 24, further comprising means for applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.

26. (Withdrawn) The vessel wall cutting instrument of Claim 24, further comprising means for applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.

27. (Withdrawn) The vessel wall cutting instrument of Claim 24, further comprising means for applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.

28. (Withdrawn) The vessel wall cutting instrument of Claim 18, wherein the moving means further comprises an elongated, flexible, remote control comprising a flexible cable extending from the second shaft member through a flexible tube to a remote plunger adapted to be manipulated to transmit force through the flexible cable to move the second shaft member with respect to the first shaft member between the retracted position and the extended position.

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29. (Withdrawn) The vessel wall cutting instrument of Claim 28, further comprising means for applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.

30. (Withdrawn) The vessel wall cutting instrument of Claim 28, further comprising means for applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.

31. (Withdrawn) The vessel wall cutting instrument of Claim 28, further comprising means for applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.

32. (Original) The vessel wall cutting instrument of Claim 18, further comprising means for applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.

33. (Original) The vessel wall cutting instrument of Claim 18, further comprising means for applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.

34. (Original) The vessel wall cutting instrument of Claim 18, further comprising means for applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.

35. (Withdrawn) A method of making an elongated slit through a vessel wall and into a lumen of a body vessel of a patient substantially in alignment with the axis of the body vessel comprising the steps of:

providing a vessel wall cutting instrument having first and second cutting blades, wherein the first cutting blade has a substantially straight first cutting edge extending along a

trailing side of the first cutting blade, a cutting tip at the first cutting blade free end, and an atraumatic blunt surface along the leading side of the first cutting blade, and the second cutting blade has a second cutting edge extending along a leading side of the second cutting blade;

obtaining access to an exposed exterior surface of the vessel wall;

separating the first and second cutting blades apart;

advancing the blunt leading side of the first cutting blade against the exposed exterior surface of the vessel wall substantially in alignment with the vessel wall axis to depress the vessel wall and dispose a cutting tip of the first cutting blade against the exposed exterior surface of the depressed vessel wall;

moving the first cutting blade laterally to pass the cutting tip of the first cutting blade through the vessel wall and into the lumen of the body vessel substantially in alignment with the vessel axis;

applying the first cutting edge of the first cutting blade against an interior surface of the vessel wall substantially in alignment with the vessel lumen; and

moving the first and second cutting edges substantially in side-by-side alignment to shear the vessel wall therebetween and form a slit therein.

36. (Withdrawn) The method of Claim 35, wherein the moving step further comprises moving the second cutting blade toward and alongside the first cutting blade as the first cutting edge of the first cutting blade is applied against an interior surface of the vessel wall substantially in alignment with the vessel lumen.

37. (Withdrawn) The method of Claim 36, further comprising applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.

38. (Withdrawn) The method of Claim 36, further comprising applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.

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39. (Withdrawn) The method of Claim 36, further comprising applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.
40. (Withdrawn) The method of Claim 35, further comprising applying suction to the body tissue alongside the body vessel to stabilize the body vessel from movement.
41. (Withdrawn) The method of Claim 35, further comprising applying an occlusion frame against the body vessel and body tissue alongside the body vessel to compress the body vessel lumen and inhibit blood loss through the elongated slit.
42. (Withdrawn) The method of Claim 35, further comprising applying compressive force to the body vessel alongside the body vessel to compress and stabilize the body vessel from movement.
43. (Withdrawn) The method of Claim 35, wherein the body vessel is a coronary artery extending along the epicardium of the heart.
44. (Withdrawn) The method of Claim 43, further comprising applying suction to the epicardium alongside the coronary artery to stabilize the coronary artery from movement of the heart.
45. (Withdrawn) The method of Claim 43, further comprising applying compressive force to the epicardium alongside the coronary artery to stabilize the coronary artery from movement of the heart.

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46. (Withdrawn) The method of Claim 43, further comprising applying an occlusion frame against the coronary artery and epicardium alongside the coronary artery to compress the coronary artery lumen and inhibit blood loss through the elongated slit.